Overview state guidance on smallpox vaccine adverse events monitoring and response:

The role of the AE coordinator

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CDC Immunization

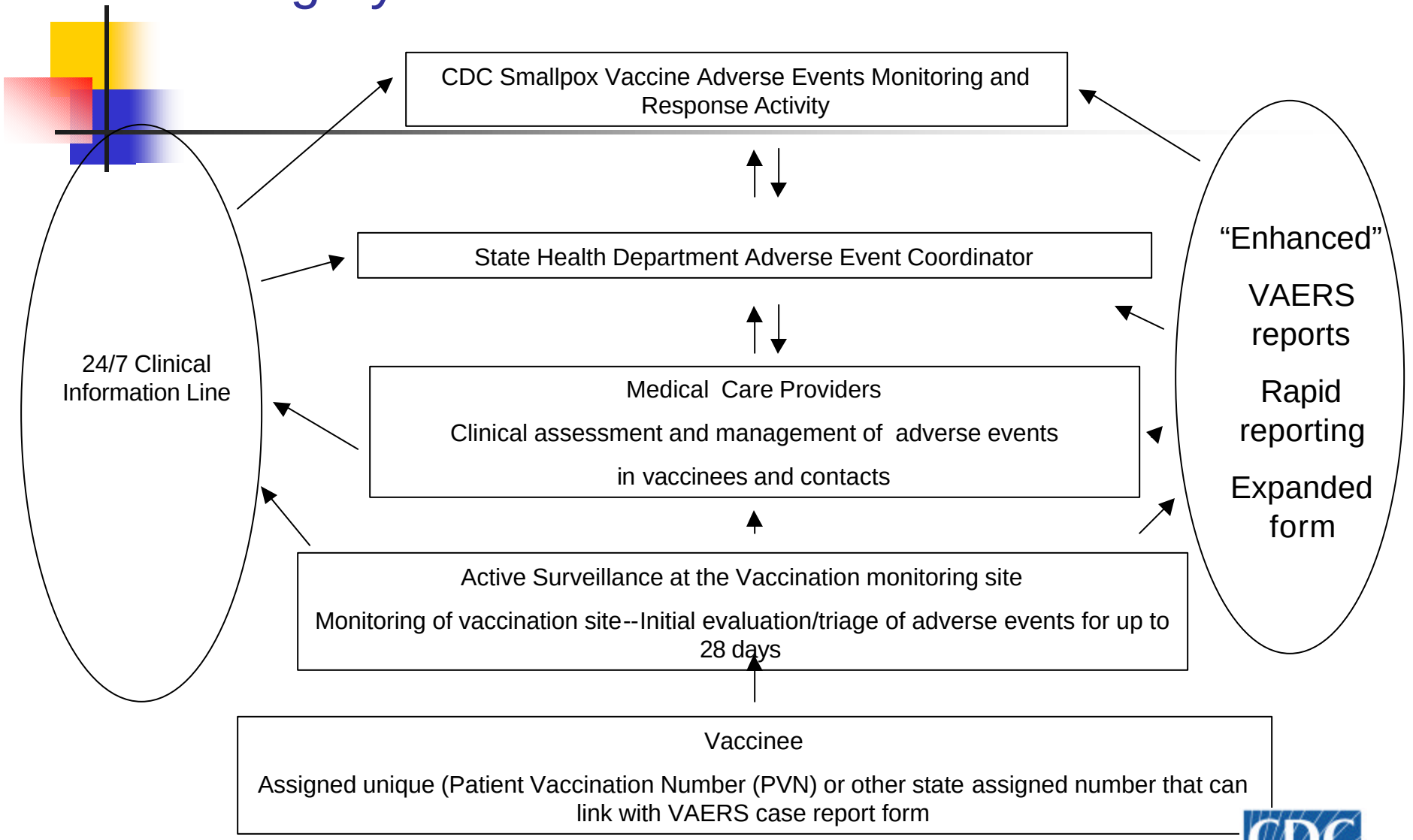
IOM Report – 1/22/03

- "Ensuring that adverse events are identified, treated, quantified and evaluated will be critical to the success of the pre-event smallpox vaccination program."
  - Early recognition, evaluation and appropriate treatment of AEs
    - Detecting adverse reactions and evaluating them early will be the first step in this process.

IOM Report

- “the Committee strongly recommends that active surveillance for adverse events be employed....”

Smallpox Vaccine Adverse Events Monitoring System



State Smallpox Vaccine Adverse Events Coordinator, Role/Responsibilities

- Establish and coordinate smallpox adverse events reporting and tracking system
  - Active surveillance for adverse events
- Facilitate training and communication with persons and organizations responsible for adverse event reporting and management
- Identify and track clinically significant adverse events in collaboration with CDC
  - Case investigation to verify diagnosis
  - Monitor clinical course and outcome
- Facilitate VIG/Cidofovir release as appropriate

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Monitoring for Adverse Events

- Provide 24/7 coverage
- Establish Active Surveillance
  - to detect and document the occurrence of clinically significant AEs
- Vaccine Recipients
  - Given instructions at time of vaccination
    - Day 6-8 – take check and assess for AE
    - Day 21-28 – assess for AE
    - Their contacts?

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Identification of Adverse Events

- How will adverse events be detected?
  - Public Health Response Team
    - Self –reporting via hotline
    - Health Care Provider
  - HCW – monitoring of vaccination site
    - Use of the Web-based hospital system

Evaluation of Suspected Adverse Events

- Who will be responsible for the evaluation of suspected adverse events?
  - Health Care Workers
    - Occupational Physicians
    - Subspecialists
  - Public Health Response Teams
    - Physicians – state or local
  - What is the role of the State or the Clinician Information Lines

Management and Tracking of Clinically Significant Adverse Events

- Plan for requesting of VIG/Cidofovir:
  - Who is responsible for requesting?
  - Who in the SHD is responsible for follow-up including the IND paperwork?
- Tracking of Clinically Significant AEs
  - A designated person at the State Health Department should be responsible for tracking

Reporting of Adverse Events

- Who will be responsible for filing VAERS report?
  - Providers
  - State Health Department
- How will reporting be conducted?
  - Electronically
  - Paper – Faxing

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Reports

- Several reports will be generated from multiple place (Internal, local health department, CDC)
- Need to coordinate so information provided is the same – date-time stamp, share reports

Communication

- Communicate with medical organizations
- Communicate with media on vaccine safety issues
- Inform medical providers about smallpox vaccination program
  - Where to obtain information
  - What and where to report

Conclusion

- The role of the AE coordinator is key to the success of the Adverse Events Monitoring System